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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,898	03/15/2001	Bruce Bryan	LUME 48487	4894

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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,898

Applicant(s)

BRYAN ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-704.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13,22,38-50,57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) 14-21,23-37,51-56 and 59-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,22,38-50,57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

Claims 1-77 are pending.

Applicants' amendment filed 7 October 2004, which, amends claims 1-3, 6-7, 9-11, 38, 41, 45, 50 and 57-58 has been entered. Also, the applicants' request (filed 13 September 2004) for exertion of time of three months has been entered. Note that claims 14-21, 23-37, 51-56 and 59-77 are withdrawn from consideration by examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Thus, the pending claims 1-13, 22, 38-50 and 57-58 are under examination in this Office action.

Please note that the objection to the specification/claims, and claim rejection under 35 USC 103 are withdrawn.

Claim rejection under 35 USC 103 is withdrawn because the invention of Patent 6232107 does not disclose a nucleotide sequence of the claimed polynucleotide (see the patent claims 23-24) which reads on the instant SEQ ID NO:27 of the current application, and because 6232107 does not have the polynucleotide isolated from *Renilla reniformis* in hand, which encodes *Renilla reniformis* GFP.

IDS

Acknowledgment is made of receiving the three boxes of the references cited in PTO 14449 of the IDS filed 19 March 2002. Examiner has considered the references cited in the PTO-1449 of the IDS filed 13 September 2004, which is a resubmitted IDS of that filed 19 March 2002.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 10-11, 45, 47 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the term "SSPE"; the recitation is indefinite because the specification does not define the said term. It is not apparent whether or not the "SSPE" refers to (i) tetrapeptide "Ser-Ser-Pro-Glu" or a buffer comprising solution Sodium Chloride, Sodium Phosphate, and Na₂EDTA. Also, the recitation of (item (b)) "high stringency having a percentage mismatch of ..." is unclear because the phrase "high stringency" definition refers to a reaction conditions - notably temperature, salt, and pH which dictate the annealing of single-stranded DNA/DNA, DNA/RNA, and RNA/RNA hybrids, and because the *percentage mismatch* of base-pairing of nucleic acid duplexes does not necessarily reflect or define the high stringency condition thereof.

Claim 10 appear missing "further" before "comprising". Without "further" the claim is awkward. Also, claim 10 should make it clear that whether or not "selectable marker" is a marker for gene cloning, e.g., Ampicillin resistance gene. Note that the specification does not the phrase "selectable marker".

Claim 11 is indefinite because it is not clear as to whether or not the recitation "nucleotide sequence encoding luciferase" is the same as the "selectable marker" sequence set forth in claim 10 because luciferase may also be used as a marker.

Claim 45 does make it clear that whether or not "GFP" is *Renilla reniformis* GFP recited in claim 38 from which claim 45 depends.

Claim 47 recites "fluorescent protein"; it is not clear as to whether or not the recited

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fluorescent protein refers to any fluorescent protein rather than *Renilla reniformis* GFP in claim 38. Note that the claim as written "fluorescent protein" is not specific but rather encompasses any fluorescent protein.

Claim 50 as amended recites "the cell of claim 9", the recitation lacks antecedent basis in claims 9 and 1 which claim 50 depends.

Claim Rejection -Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-13, 22, 38-50 and 57-58 are rejected under the judicially created doctrine of the obviousness-type double patenting of the claims 22-24, 27, 29-37 and 56-58 in US Pat. No. 6232107. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the patent claims 22-24, Bryan et al. disclose an isolated *Renilla reniformis* polynucleotide comprising a coding sequence encoding a *Renilla reniformis* green fluorescent protein (GFP). While the polynucleotide sequence encoding the GFP protein sequence is not described in Bryan et al. patent, the encoded protein sequence reads on SEQ ID NO: 27 of the

current application because the nucleic acid sources from where the GFP protein are encoded are identical between the current application (claims 1-3) and the 6232107 patent. Thus, the polynucleotide disclosed by Bryan et al. is an obvious over the polynucleotide that encodes SEQ ID NO: 27 of the current application claims 1-3. Thus, claims 22-24 of 6232107 disclose the common subject matter of claims 1-3 of the current application, i.e., an isolated Renilla reniformis polynucleotide comprising coding sequence encoding a Renilla reniformis green fluorescent protein (GFP).

Since claims 22-24 of 6232107 disclose that the isolated polynucleotide is a nucleic acid construct encoding a fusion protein, i.e., Renilla reniformis GFP and luciferase; wherein the luciferase is Renilla mulleri luciferase of SEQ ID NO:17, the subject matter of the claims 22-24 is an obvious variation of the instant claims 38 and 47-48.

Claims 22 and 27 of 6232107 teach that the luciferase in the said construct (claim 22) is of protein sequence of SEQ ID NO:17 which is from Renilla mulleri (see the patent claim 27 and column 104 where describes SEQ ID NO:17); the luciferase polypeptide sequence shown in the patent SEQ ID NO:17 is identical to the amino acid sequence of SEQ ID NO:17 recited in the instant claim 41. Thus, the subject matter of claims 22 and 27 is an obvious variation of the instant claim 41.

Since the luciferase in the said construct inherently acts as a reporter (see column 85, lines 33-47 of 6232107), the patent claim 22 covers the subject matter set forth in the instant claim 22.

The patent claims 22-24 also covers the common subject matter set forth in the instant claim 46, which sets forth the luciferase-GFP fusion protein is encoded by a polycistronic

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message, because (i) the polycistronic message refers to mRNA carrying information for the synthesis of more than one protein, and (ii) the polynucleotide encoding the fusion protein in the said construct is a polycistronic mRNA (an inherent property of said polynucleotide).

The patent claims 29 and 30 set forth that the said nucleic acid construct of claim 22 is DNA or RNA, respectively, which is common subject matter of that of the instant claims 4-5 and 42-43.

The patent claim 37 sets forth a nucleic acid probe comprising at least 30 nucleotides wherein the probe encodes peptide sequence of SEQ ID NO:25 that is 100% identical to amino acids 71-109 of SEQ ID NO:27 of the instant application, which is common subject matter of the instant claims 6-8.

The patent claims 31-32 set forth that the above-mentioned construct is a plasmid which is an expression vector comprising a promoter, a selectable marker wherein the nucleotide sequence encoding *Renilla reniformis* GFP is operatively linked to said promoter (see the patent claim 32), a cloning site (see Example 10). Thus, the subject matter of the patent claims 31-32 is an obvious variation of that of the instant claims 9-10 and 44-45.

In addition, the patent claim 32 sets forth that the plasmid encodes a fusion protein of the luciferase and GFP, which is common subject matter of the instant claim 11.

The patent claims 56-58 of 6232107 set forth the luciferase in the said construct (claim 22) wherein the luciferase is a *Gaussia princeps* luciferase, which is common subject matter of the instant claims 39-40.

The patent claims 33-34 of 6232107 set forth a recombinant host cells comprising the above-mentioned plasmid, and the host is a bacterial cell or a yeast cell or a fungal cell or a plant

cell or an insect cell or an animal cell (see the patent claims 33-34), which is common subject matter of the instant claims 12-13 and 49-50.

The patent claims 35-36 set forth that the nucleotide sequence encoding the luciferase and GFP are not contiguous (see the patent claim 35), and that the above-mentioned construct further comprises a nucleotide sequence encoding a ligand-binding domain of a protein (see the patent claim 36). Thus, the subject matter of 6232107 claims 35 and 36 is an obvious variation of that of the instant claims 57 and 58, respectively.

Therefore, the instant application and the US Pat. No. 6232107 claims are not patentably distinct from each other.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant's response to the claim Rejection -Obviousness Type Double Patenting

The response filed 7 October 2004 discusses claims 1 and 5 of 6232107 and compares the said claims with the instant claims 1-13, 22, 38-50 and 57-58; and, infers that because 6232107 claims do not disclose the same subject matter, i.e. a polynucleotide encoding *Renilla reniformis* GFP, the 6232107 is not an obvious variation over the instant claims (see page 27, the 2nd and 3rd

paragraphs). The applicants' argument is found to be unpersuasive because the said rejection does not compare 6232107 claims 1 and 5 with said instant claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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Samuel Wei Liu, Ph.D.

November 23, 2004